IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **CASES LISTED IN PLAINTIFFS' EXHIBIT A [Doc. No. 8562]**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE RICHARD WASSERMAN, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this opposition to Plaintiffs' motion to exclude the expert testimony of Richard Wasserman, M.D. Dkt. 8562, 8563. For the reasons set forth below, the motion fails and should be denied.

Argument

Dr. Wasserman, a board-certified OB-GYN and urogynecologist, is well-qualified to offer expert testimony regarding the TVT family of devices, including TVT, TVT-O, TVT-Abbrevo, and TVT-Exact.

I. Dr. Wasserman's testimony is reliable and relevant.

In order to support their argument for exclusion, Plaintiffs repeatedly take Dr. Wasserman's testimony out of context and omit relevant related testimony.

First, Plaintiffs appear to claim that Dr. Wasserman's treatment of the TVT family of devices as equivalent is inappropriate. Yet Dr. Wasserman's testimony on this point is clear and supported by sound medical analysis. As he explains, while the device may be inserted by varying methods and have slightly different designs, they can analyzed as equivalents on many

of the points at issue in this litigation: "[t]he safety profile for the actual sling is similar throughout," and "based upon the literature, they are all kind of the same in regards to risks of the sling itself." Wasserman Dep., attached as Ex. A, at 41:24-43:18. However, the placement of the sling may be different and involve different considerations and risks inherent in the surgery. *See id*. Dr. Wasserman's opinion is that the TVT midurethral slings – the devices themselves – are equivalently safe as macroporous polypropylene midurethral slings, without consideration of the surgical approach used. Indeed, even the FDA has addressed "surgical mesh slings for SUI" (which would include TVT, TVT-O, TVT-Abbrevo, and TVT-Exact) as a group, functionally equivalent, discussing the relevant risks and consideration common to these product. *See* Considerations about Surgical Mesh for SUI (FDA), last accessed 8/29/19 https://www.fda.gov/medical-devices/urogynecologic-surgical-mesh-implants/considerations-about-surgical-mesh-sui.

Second, Plaintiffs claim that Dr. Wasserman "made it clear during his deposition that he does not trust the opinions of any one individual," and that somehow this means his own testimony should be excluded. Dkt. 8563 at 4. Plaintiffs' argument again takes the testimony out of context, misinterprets it, and thus reaches an illogical conclusion. It is clear from Dr. Wasserman's testimony that he, like any highly trained scientist, would not rely on the unique statement of one individual alone in order to reach a scientifically sound conclusion. *See, e.g.*, Ex. A, Wasserman Dep. at 29:21-30:3 ("[W]hen I review material for forming my opinion, I would not base it on the one specific individual's conclusions."). As example for this premise, Plaintiffs cite Dr. Wasserman's testimony that he does not consider the individual opinions of Ethicon's medical directors and employees as "high quality" evidence. *See* Ex. A at 27:10-31:19. Dr. Wasserman's testimony is clear, however, that he places more weight on higher quality,

"level 1" material, such as Cochrane databases, meta-analyses, and statements from professional societies that analyze the data from hundreds of reliable sources to reach recommendations and conclusions. *Id*. at 28:4-19. In other words, because he is a scientist and looking for the best scientific evidence available, he will consider these "level 1" studies and statements as *more* reliable than the statement of one specific individual when making his conclusions. Dr. Wasserman is not offering a bald conclusion based on mere *ipse dixit* of one individual. He has relied on a thorough review of the relevant literature, case studies, databases, and his own experience—he is not one lone individual offering an unsupported opinion.

Plaintiffs also egregiously mischaracterize Dr. Wasserman's testimony that he is "making it up as I go" and "guessing about these things." *See* Ex. A at 236:4-236:14, 237:15-18. These cherry-picked quotes were made in response to Plaintiffs' counsel presentation of several hypothetical situations to Dr. Wasserman that he had not encountered in his practice or in his study of the TVT family of products. *Id*. at 233:25-237:18. In examining the full context of Dr. Wasserman's testimony, it is clear that he does not know how to respond to these hypothetical questions because they are not supported by the scientific literature or by his own clinical practice. Plaintiffs' suggestion that Dr. Wasserman is not "taking the scientific process seriously" by not answering Plaintiffs' counsel's hypothetical questions – which Dr. Wasserman described as "goofy" in light of his actual experience – is without merit. See Dkt. 8563 at 6, Ex. A at 237:12-237:18.[1] Certainly, Dr. Wasserman clarified why he was unable to answer the questions in the way Plaintiffs apparently wanted it to be answered; namely, he was wholly unfamiliar with this situation in either the relevant scientific literature or his own clinical experience.

[1] For instance, Plaintiffs' counsel asked whether Dr. Wasserman would deem it to be evidence of physical degradation if he "picked up the mesh and it completely fell apart in [his] hands" or if there were "particles floating around in the box that aren't attached to the mesh." Ex. A at 234:16-237:18. This is not a scenario presented by the medical records or data in these cases. Accordingly, Dr. Wasserman responded that he did not know because he had never experienced that situation, and he would be guessing. *See id*.

Finally, Plaintiffs attack Dr. Wasserman's use of a different manufacturer's retropubic and obturator approach mid-urethral slings. As Dr. Wasserman testified, his current employer has a contract to use a different manufacturer's products, but "[w]ere [the TVT devices] available at my hospitals that I work out of, I would absolutely use them." Ex. A at 48:21-49:22. Dr. Wasserman's Report makes clear that he has performed "thousands of retropubic mid-urethral sling procedures over the past 13 years, including both TVT and TVT-Exact implant procedure," as well as "hundreds of trans-obturator mid-urethral sling procedures, including both TVT-O and TVT-Abbrevo implant procedures." Ex. B to Motion at 2. Dr. Wasserman's current use of a different manufacturer's mid-urethral slings does not suddenly render his opinions regarding the TVT family of products unreliable.[2]

Plaintiffs' argument boils down to a logical fallacy: because Dr. Wasserman does not rely solely upon the opinion of one individual, he is not an individual whose opinion the jury can rely upon. But this is simply not how the *Daubert* analysis works. A physician's "knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*." *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 714 (S.D.W. Va. 2014). Plaintiffs do not dispute that Dr. Wasserman reviewed the relevant scientific literature and relied on his own knowledge and prior clinical experience to provide these opinions. To the extent Plaintiffs disagree with Dr. Wasserman's rejection of certain opinions, such rejection goes to weight and not admissibility. *See Trevino v. Boston Scientific Corp.*, 2016 WL 1718836, *8 (S.D. W. Va. Apr. 28, 2016) (finding that that "to the extent the defendant challenges the reasons

[2] Plaintiffs also criticize Dr. Wasserman's so-called inability to define the "standard of care" and claim that his statement that physicians using a Burch procedure are not committing malpractice is contradictory. Dr. Wasserman's testimony is clear on this point: he believes "the standard of care today for stress urinary incontinence is a midurethral sling." Ex. A at 96:1-97:6. But Dr. Wasserman is careful not to criticize other physicians and other surgeons, and he does not believe a surgeon that chooses a Burch procedure is committing malpractice. *Id.* at 97:7-97:21. Plaintiffs attempt to conflate two concepts – the standard of care meaning the "procedure out there that holds less morbidity, that works better" and the legal standard of care in a medical malpractice case. *See id*. at 97:22-100:6.

Dr. Margolis offers for not relying on certain studies, such challenges go to the weight of Dr. Margolis's opinions, not their admissibility" and that "[t]he defendant is free to cross-examine Dr. Margolis regarding studies that cut against his opinions").

II. Dr. Wasserman is qualified to opine as to the physical properties of the mesh.

Plaintiffs object to Dr. Wasserman's testimony regarding the physical properties of the mesh, including the physical properties of the polypropylene mesh; the lack of foreign body reaction caused by the mess or cytotoxicity of the mesh; the lack of particle, loss, fraying, curling, or roping of the mesh; and the lack of degradation of the mesh in the body. As Plaintiffs admit, this Court has allowed experts – including urogynecologists like Dr. Wasserman – to testify regarding the physical properties of mesh. There is no substantive difference between Dr. Wasserman's training and experience and the experience of the urogynecologists this court has allowed to testify regarding these properties.

In *Trevino v. Boston Scientific Corp.*, 2016 WL 2939521, at *45 (S.D. W. Va. May 19, 2016), the plaintiff argued that Dr.Michael Douso, a urogynecologist, was not qualified to testify about the physical properties of mesh and to offer opinions about degradation and similar topics because he was not a biomaterials or polymer science expert. In rejecting this challenge, the Court stated as follows:

> As to qualification, Dr. Douso is a practicing urogynecologist, and he is board-certified in obstetrics and gynecology. He has extensive experience with BSC's produces for treating SUI and POP, including use of the Prefyx and Uphold mesh sling devices. Dr. Douso has had extensive experience teaching minimally invasive surgical techniques and procedures to physicians across the United States, including implantation of the defendant's polypropylene mesh devices. Simply because Dr. Douso is not an engineer, chemist, or biomechanical expert does not render him unqualified to testify that he has not experienced mesh degradation, contraction, or a foreign body response in his practice. "One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc.*, 878 F.2d at 799. I **FIND** that Dr. Douso's extensive experience qualified

> him to testify that he has not experienced certain alleged physical properties in the defendant's Uphold and Prefyx devices.

2016 WL 2939521, at *45 (other citations omitted); *see also id.* at *5 (finding that urologist Niall Galloway's "clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage and contraction"); *id.* at *33 (allowing testimony of defense expert Patrick Culligan, M.D.); *Huskey*, 29 F. Supp. 3d at 706-07, 735 (rejecting similar challenges to plaintiff expert Bruce Rosenzweig, M.D., and defense expert urogynecologist Harry Johnson, M.D.); *Tyree*, 54 F. Supp. 3d at 550, 585 (rejecting similar challenge of plaintiff expert Donald Ostergard, M.D. and defense expert Lonny Green, M.D.); *Jones v. Bard, Inc.*, No. 2:11–cv–00114, (Dkt. 391), pp. 6–9.

Dr. Wasserman's clinical experience and training as a board-certified urogynecologist certainly qualify him to testify regarding his experience with the physical properties of the TVT family of devices. Dr. Wasserman's report contains numerous references to the scientific evidence and publications Dr. Wasserman relies on in order to make these conclusions – as well as his reliance on his own clinical experience with the TVT family of products over the past thirteen (13) years.

Plaintiffs attempt to take Dr. Wasserman's deposition testimony out of context to attack the well-supported conclusions in his report. For each of these excerpts, Plaintiffs suggest that Dr. Wasserman's testimony is incorrect or ignores the scientific literature without providing any foundation for that suggestion. Plaintiffs claim that Dr. Wasserman is unqualified because "he knows nothing about the additives that go into the polypropylene mesh," because he "had no support for his opinion that the Prolene material used in Ethicon's meshes is safe and effective," because he could not answer a hypothetical question regarding what he would do if he encountered a new TVT device "with the particles already having fallen off," and because he

discounted studies from the 1990s Plaintiffs claim show cytotoxicity. *See* Dkt. 8563 at 9-11. Yet for each of these, Plaintiffs ignore the myriad of scientific studies and literature Dr. Wasserman did identify and rely on and his report, while Plaintiffs also fail to identify the studies or evidence Dr. Wasserman allegedly failed to review. Plaintiffs certainly have not shown that Dr. Wasserman "fail[ed] to account for contrary scientific literature and instead 'selectively [chooses] his support from the scientific landscape." *Tyree v. Boston Sci. Corp*., 54 F. Supp. 3d 501, 520 (S.D.W. Va. 2014) (GOODWIN, J.), *as amended* (Oct. 29, 2014) (citing *In re Rezulin Products Liab. Litig*., 369 F. Supp. 2d 398, 425 (S.D.N.Y.2005)). Any apparent contradictions are better addressed on cross at trial and do not render Dr. Wasserman's opinions unreliable and inadmissible.

For the studies Plaintiffs claim show cytotoxicity of the TVT device in the 1990s, moreover, for instance, Dr. Wasserman was unable to identify additional cytotoxicity testing *done by Ethicon and Johnson and Johnson*, which was Plaintiffs' counsel's actual question. *See* Ex. A, Dep. Tr. of Dr. Wasserman at 249:4-17. Dr. Wasserman clarified the basis for his opinion, which is supported by the bulk of the level 1 data, that "as a clinician, cytotoxicity doesn't happen," and the "very, very low erosion rate, [and] very low exposure rate" indicate that the mesh is not cytotoxic. *Id*. at 249:19-250:15.

III. Dr. Wasserman may opine regarding the complication rates of laser-cut mesh and mechanically cut mesh.

Dr. Wasserman's opinions regarding the lack of difference in the performance of mid-urethral slings based on how they are cut should be allowed. In Dr. Wasserman's Report, he cites several articles summarizing studies examining this very question, including meta-analyses and a Cochrane review. *See* Ex. B to Motion at 14, n. 54, 16 n. 67. Dr. Wasserman concludes, based on these studies and his own clinical experience, that the mechanically cut and laser-cut meshes

demonstrate no clinically significant differences. Plaintiffs' argument that Dr. Wasserman's opinion is based on his own beliefs about complication rates in his practice is simply without merit.

IV. Dr. Wasserman is qualified to opine as to the risks known to pelvic surgeons.

Plaintiffs argue that Dr. Wasserman is not qualified to offer opinions regarding the adequacy of the Instructions for Use ("IFUs") for the TVT family of products. As this Court has previously allowed, Dr. Wasserman will testify regarding what risks exist (or presumably do not exist) and whether they are listed in the IFU. Additionally, Dr. Wasserman's testimony regarding commonly-known risks is proper and admissible. Dr. Wasserman carefully considered each of the alleged risks identified by Plaintiffs as risks that should have been included in the IFU. Dr. Wasserman concluded that these risks were either included in the relevant IFUs for the TVT family of products, were risks that are commonly known to pelvic surgeons, or are risks not observed in the published literature or in Dr. Wasserman's practice. *See* Ex. B to Motion at 14, 17-18.

"[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *15 (S.D.W. Va. Apr. 24, 2015) (quoting *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09–md–02100, 2011 WL 6301625, at *11 (S.D.Ill.Dec.16, 2011)). Dr. Wasserman has reviewed the IFUs and identified potential complications included in the IFUs, including "the risk of erosion, extrusion, fistula formation, inflammation, de novo detrusor instability, infection, lower urinary tract obstruction, and punctures or lacerations of vessels, nerves, bladder, urethral or bowel, which may necessitate surgical repair." Ex. B to Motion at 17.

Dr. Wasserman further noted that "[t]he risks of pelvic surgery have been reported extensively in the peer-reviewed literature for many decades." *Id*.

The important question here is whether Dr. Wasserman's testimony was consistent with the law to be applied to the case, and not whether he himself could articulate the governing legal standard. If he had attempted to do that, his testimony would be excluded. Dr. Wasserman is not making any such attempt with his opinions on Ethicon's IFUs and warnings.

In addition, Dr. Wasserman's testimony on Ethicon's IFUs and warnings is consistent with the governing legal standard and should therefore be admitted in its entirety. The legal principle that controls here is that a device manufacturer's duty to warn of adverse events does not include a duty to warn of risks commonly known to the surgeons who use the device. As stated generally in the Restatement (Third) of Torts: Product Liability §2, cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users." *See also* Restatement (Second) of the Law of Torts §§388(b), 402A, cmt. j; *Roney v. Gencorp*, 654 F. Supp. 2d 501 (S.D. W. Va. 2009) (adopting "sophisticated user" defense in §388). The test is an objective test that depends on the knowledge of foreseeable users generally, and not on the knowledge of person whose use is at issue in the particular case. *Johnson v. American Standard, Inc*., 179 P.3d 905, 914 (Cal. 2008) (sophisticated user "knew or should have known" of the danger).

This limitation on the duty to warn is recognized in medical cases as well. There is no duty to warn of risks commonly known to implanting surgeons. *See Brooks v. Medtronic, Inc*., 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers "not well known to the

medical community."). In fact, the FDA device regulations say that information may be omitted from labeling:

> if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device.

21 C.F.R. §801.10(c) (emphasis added). *See also Wright ex rel. Trust Co. of Kansas v. Abbot Laboratories, Inc.*, 259 F.3d 1226, 1234 (10th Cir. 2001) (drug company had no duty to warn hospital of the danger of stocking different concentrations of saline solution in the same place); *Brown v. Drake-Willock Intern. Ltd.*, 530 N.W. 2d 510, 516 (Mich. App. 1995) (physician was sophisticated user of dialysis machine).

The IFUs at issue here restrict the class of surgeons who are to use the devices. They contemplate that users will be familiar with traditional surgical techniques used to treat stress urinary incontinence. The TVT IFU says, "Users should be familiar with surgical techniques for bladder neck suspension and should be adequately trained in implanting the TVT system." (ETH.MESH.00875483 (attached as Ex. B)). The TVT-O IFU says it should be used "only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the Gynecare TVT Obturator device." (ETH.MESH.12534283 (attached as Ex. C)).

So the important question with respect to the plaintiffs' failure to warn claim is what "hazards" were "commonly known" to surgeons familiar with traditional non-mesh SUI surgery and mesh surgery before TVT or TVT-O were introduced. Dr. Wasserman is qualified by his experience and his examination of the literature to identify the risks that are commonly known and give the opinion that the IFU included those that might not be.

CONCLUSION

For the reasons set forth in this Response, Ethicon respectfully requests the Court deny Plaintiffs' Motion to Exclude the General Causation Opinions of Defense Expert Richard Wasserman, M.D.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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